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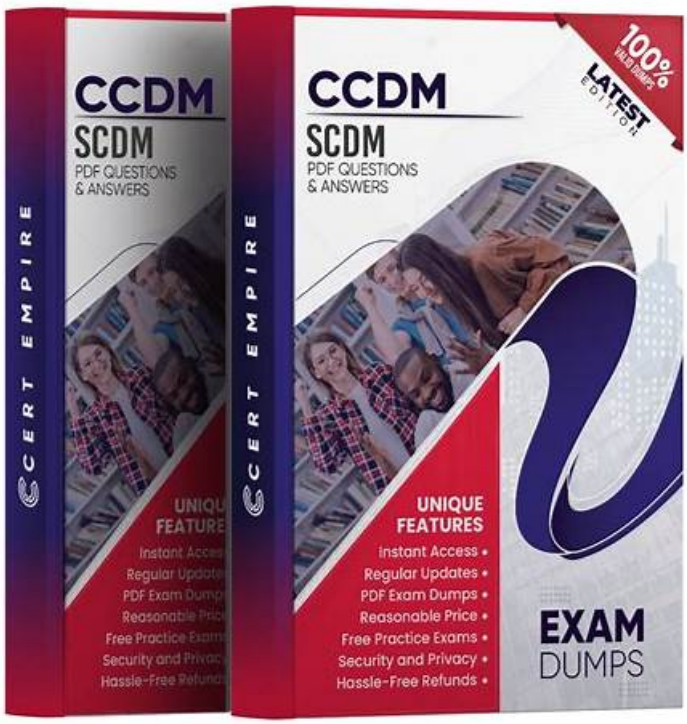

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SCDM Certified Clinical Data Manager Sample Questions (Q150-Q155):

NEW QUESTION # 150
According to ICH E6, developing a Monitoring Plan is the responsibility of whom?

- A. Sponsor
- B. CRO
- C. Monitor
- D. Data Manager

Answer: A

Explanation:
According to ICH E6(R2) Good Clinical Practice (GCP), Section 5.18.1, the Sponsor is ultimately responsible for developing and implementing the Monitoring Plan.
The Monitoring Plan defines:
The extent and nature of monitoring (e.g., on-site, remote, risk-based).
The responsibilities of monitors.
The communication and escalation procedures for data quality and protocol compliance.
While the CRO (B) or Monitor (D) may perform monitoring activities under delegation, the Sponsor retains legal accountability for ensuring a compliant and effective plan is developed and maintained. The Data Manager (C) may contribute by outlining data review workflows, but is not responsible for authoring or owning the plan.
Therefore, option A (Sponsor) is the correct answer.
Reference (CCDM-Verified Sources):
ICH E6(R2) GCP, Section 5.18.1 - Purpose and Responsibilities for Monitoring SCDM GCDMP, Chapter: Regulatory Compliance and Oversight, Section 5.3 - Sponsor Responsibilities in Monitoring and Quality Assurance FDA Guidance for Industry: Oversight of Clinical Investigations - Sponsor Responsibilities (2013)

NEW QUESTION # 151
Which type of edit check would be implemented to check the correctness of data present in a text box?

- A. Back-end check
- B. Front-end check
- C. Programmed check
- D. Manual Check

Answer: B

Explanation:
A front-end check is a type of real-time validation performed at the point of data entry-typically within an Electronic Data Capture (EDC) system or data entry interface-designed to ensure that the data entered in a text box (or any input field) is valid, logically correct, and within expected parameters before the user can proceed or save the record.
According to the Good Clinical Data Management Practices (GCDMP, Chapter on Data Validation and Cleaning), edit checks are essential components of data validation that ensure data accuracy, consistency, and completeness. Front-end checks are implemented within the data collection interface and are triggered immediately when data are entered. They prevent invalid entries (such as letters in numeric fields, out-of-range values, or improper date formats) from being accepted by the system.
Examples of front-end checks include:
Ensuring a numeric field accepts only numbers (e.g., weight cannot include text characters).
Validating that a date is within an allowable range (e.g., not before the subject's date of birth).
Requiring mandatory fields to be completed before moving forward.
This differs from back-end checks or programmed checks, which are typically run later in batch processes to identify data inconsistencies after entry. Manual checks are human-performed reviews, often for context or data that cannot be validated automatically (e.g., narrative assessments).
Front-end edit checks are preferred wherever possible because they prevent errors at the source, reducing the number of downstream data queries and cleaning cycles. They contribute significantly to data quality assurance, regulatory compliance, and efficiency in data management operations.
Reference (CCDM-Verified Sources):
Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 6.2 - Edit Checks and Real-Time Data Validation FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6 - Data Entry and Verification Controls ICH E6 (R2) Good Clinical Practice, Section 5.5 - Data Handling and Record Integrity CDISC Operational Data Model (ODM) Specification - Edit Check Implementation Standards

NEW QUESTION # 152
All range and logic checks have been resolved in a study. An auditor found discrepancies between the database and the source.

Which reason is most likely?

- A. Data were changed after the checks were run
- B. Data were not abstracted correctly from the source
- C. The discrepant data values were logical and in range
- D. The auditor made an error

Answer: B

Explanation:
Even when all range and logic checks are successfully resolved, discrepancies may still exist between the clinical database and the source documents. This typically indicates an error in data abstraction or transcription, meaning that data were incorrectly entered or extracted from the source records during the data entry or verification process.
According to the Good Clinical Data Management Practices (GCDMP, Chapter on Data Validation and Cleaning), data validation rules such as range and logic checks are designed to identify inconsistencies, missing data, or out-of-range values within the database itself. However, they do not verify the accuracy of data entry against the original source documents - that responsibility falls under source data verification (SDV), typically conducted by clinical monitors or auditors.
When an auditor detects discrepancies between source and database values after all edit checks have passed, the most probable explanation is that data were not transcribed correctly from the source, rather than a failure in programmed edit checks. This could occur due to human error during manual data entry, misinterpretation of the source document, or oversight during SDV.
Option C (Data were changed after checks were run) might occur in rare cases but would normally be documented in an audit trail per 21 CFR Part 11 and ICH E6 (R2) standards. Option B misinterprets the issue, since "logical and in range" values can still be incorrect relative to the source. Option A (Auditor error) is possible but statistically less likely, as source data verification follows strict, documented audit procedures.
Therefore, the most likely reason for such discrepancies is Option D: Data were not abstracted correctly from the source, emphasizing the importance of robust data entry training, dual data entry, and verification procedures.
Reference (CCDM-Verified Sources):
Society for Clinical Data Management (SCDM), Good Clinical Data Management Practices (GCDMP), Chapter: Data Validation and Cleaning, Section 6.5 - Source Data Verification and Reconciliation ICH E6 (R2) Good Clinical Practice, Section 5.18 - Monitoring and Source Data Verification FDA Guidance for Industry: Computerized Systems Used in Clinical Investigations, Section 6 - Source Data Accuracy and Audit Trails
21 CFR Part 11 - Electronic Records and Electronic Signatures, Subpart B: Audit Trails and Record Accuracy

NEW QUESTION # 153
For a study, body mass index is calculated from weight and height. Which information is needed to document the transformation?

- A. Algorithm and algorithm version associated with the calculated value
- B. Algorithm associated with the calculated value
- C. User ID making the change and reason for change
- D. Algorithm documented in the Data Management Plan

Answer: A

Explanation:
When derived or calculated variables (like Body Mass Index) are created, it is essential to document the algorithm used and its version to ensure full data traceability and reproducibility.
According to GCDMP (Chapter: Database Design and Derived Data), every derived field must include metadata describing:
The derivation algorithm (e.g., BMI = weight [kg] / height² [m²])
The version of the algorithm (if updates or revisions occur)
Any associated data sources or transformation rules
This ensures consistent calculation across systems, prevents discrepancies during regulatory submissions, and aligns with FDA and CDISC documentation expectations.
Option B lacks version control, which is critical for traceability. Option C describes audit trail data (not derivation metadata), and option D refers to broader documentation, not specific algorithm traceability.
Hence, option A (Algorithm and algorithm version associated with the calculated value) is the correct and compliant answer.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Derived Data and Algorithms, Section 5.3 - Documentation and Metadata Requirements ICH E6(R2) GCP, Section 5.5.3 - Derived Data and Validation Traceability FDA Guidance for Industry: Providing Regulatory Submissions in Electronic Format - Data Definitions (Define.xml)

NEW QUESTION # 154
Which of the following roles commonly requires data entry and update privileges in an EDC application used in a clinical study?

- A. Clinical Study Monitor
- B. EDC System Administrator
- C. Site Study Coordinator
- D. Study Statistician

Answer: C

Explanation:
In an EDC system, Site Study Coordinators are typically responsible for data entry and updates, as they are the site-level personnel who record subject data from source documents into the electronic CRFs (eCRFs).
The Good Clinical Data Management Practices (GCDMP, Chapter: EDC Systems) outlines that data entry and modification privileges should only be granted to qualified site personnel who have completed EDC system training and are listed on the study delegation log. These users directly handle patient-level data entry and correction.
In contrast:
Clinical Study Monitors (B) review and verify data but do not enter or modify it.
EDC System Administrators (C) manage user access and configuration settings, not study data.
Study Statisticians (D) work with extracted, cleaned datasets but never have data modification privileges.
Thus, option A (Site Study Coordinator) correctly identifies the role with authorized data entry and update privileges.
Reference (CCDM-Verified Sources):
SCDM GCDMP, Chapter: Electronic Data Capture (EDC) Systems, Section 5.2 - User Roles and Access Permissions ICH E6(R2) GCP, Section 4.1 - Investigator Responsibilities for Data Accuracy FDA 21 CFR Part 11 - User Access and Accountability in Electronic Systems

NEW QUESTION # 155
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